

The claim chart provided below sets forth each limitation of each of the claims 1-20 of the present application and the corresponding support in the specification for each limitation. Each of the cited paragraphs refers to paragraphs in the present application as originally filed.

Claim	Support
<p><b>Claim 1.</b> An apparatus for enhancing living tissue comprising:</p>	<p><b>apparatus for enhancing living tissue:</b>  <i>E.g.</i>, Fig. 1, "10";          "soft tissue enlargement apparatus", ¶32; and          "The dome may be conveniently located over an open wound in order to promote healing of the wound by enlarging the soft tissue under the dome. As the <u>soft tissue grows</u>, it promotes healing of the wound through acceleration of the closing thereof by soft tissue growth. As wounds may be received by a patient to any part of his body, the inventor's prior disclosed and <u>claimed invention</u> includes the use of a <u>dome over virtually any part of the human body.</u>" ¶13 (emphasis added).</p>
<p><b>Claim 1, cont'd</b> a vessel having an open end and adapted to encompass the tissue to be enhanced;</p>	<p><b>a vessel:</b>  <i>E.g.</i>, Fig. 2, "12"; and          "dome", ¶32.</p> <p><b>an open end:</b>  <i>E.g.</i>, Fig. 2, "14";          "rim", ¶32; and          "This embodiment includes a rim 14 having a surface area 34 approximately equal to the normal area 32 of <u>the dome opening</u> thereby preventing medical complications to the soft tissue as long as the pressure is properly regulated within the dome 12", ¶36 (emphasis added).</p> <p><b>and adapted to encompass the tissue to be enhanced:</b>  <i>Compare Fig. 2 with Fig. 5 with Fig 14 with Fig. 13A with Fig. 13B;</i>          "One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36; and          "A second specific embodiment is shown in</p>

	Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38.
<b>Claim 1, cont'd</b> a source of vacuum connected to said vessel; and	<b>a source of vacuum:</b> Fig. 1, "16; and "a vacuum pump assembly 16 for creating a vacuum within the dome", ¶32.  <b>connected to said vessel:</b> Fig. 1; "Although two vacuum pump assemblies 16 may be used, one <u>depending</u> from each dome 12 so as to provide different pressures in the domes, the preferred embodiment places the domes in fluid communication with a conduit 50"; ¶37 (emphasis added); Fig. 6, "64"; and "The cavity 62 between the dome 12 and sheet 60 may be evacuated as in the first general embodiment through a port 64 to apply the tensile force to the soft tissue"; ¶39.
a flexible mass affixed to the open end of said vessel to absorb the pressure exerted by said vacuum, thereby acting as a seal and force diffuser between the vessel and the tissue adjacent the periphery of said vessel.	<b>a flexible mass:</b> Fig. 7, "46"; "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or <u>other soft, conforming type material</u> ", ¶37 (emphasis added); and "the dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin"; ¶42.  <b>affixed to the open end of said vessel:</b> Fig. 7, "46"; and "A gasket 46 may also be included about the rim 14", ¶37.

to absorb the pressure exerted by said vacuum, thereby acting as a seal and force diffuser between the vessel and the tissue adjacent the periphery of said vessel:

Figs. 8-10, "46"; and

"Several forces are developed within the dome and about the rim as a result of evacuating air from the dome. A suction or tensile force  $F_s$  is developed within the dome 12 equal to the vacuum pressure  $P_1$  multiplied by the enclosed tissue surface area 30,  $A_s$ . The vector sum of the tensile force upon the tissue surface area 30 may be called the normal force  $F_1$  and is equal to the vacuum pressure multiplied by the normal area 32,  $A_1$  of the dome opening, i.e., the projected area bounded by the periphery 33, or  $F_1 = P_1 A_1$ . An opposing force  $F_2$  is imposed on the user by the rim 14 to balance the normal force  $F_1$  and is equal but opposite to the normal force. The contact pressure  $P_2$  of the rim 14 against the user is equal to this opposing force  $F_2$  divided by the annular rim surface area 34,  $A_2$ , i.e.,  $P_2 = F_2 / A_2$  or  $F_2 = P_2 A_2$ . As the magnitude of the opposing force is equal to the magnitude of the normal force,  $F_1 = F_2$  and  $P_1 A_1 = P_2 A_2$ .

Therefore, if the rim surface area 34,  $A_2$  is configured to be greater than or equal to the normal area 32,  $A_1$  at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum within the dome 12, i.e.,  $P_2 = P_1$ ", ¶34.

A "diffuser" is "one that diffuses," and "diffuse" means "to break up and distribute . . . to spread out or become transmitted esp. by contact." *Webster's Seventh New Collegiate Dictionary*. The gasket 46 absorbs the pressure exerted by the vacuum and diffuses or spreads the force created by the vacuum. Thus, the specification in paragraph 34 makes it clear that the contact pressure of the rim against the user is decreased by increasing the surface area of the rim to which the gasket is affixed.

By application of simple physics, the increased surface area spreads or diffuses the forces created by the vacuum. This is supported by the drawings (Figs. 9, 10, 11A and 11B and 12) which show the rim 14 and gasket 46 as

	<p>having much greater surface areas than the edge of the vessel (dome 12).</p> <p>The limitation of "seal" is supported by the statement, "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and <u>enhance the seal about the rim</u>", ¶37 (emphasis added).</p> <p>The above support from the specification makes clear that the gasket 46 is a flexible mass, is affixed to the open end of the vessel, absorbs the pressure exerted by the vacuum, and acts as both a seal and a force diffuser between the vessel and the tissue adjacent the periphery of the vessel.</p>
<p><b>Claim 2.</b></p> <p>The apparatus in accordance with claim 1, wherein said vessel has a shape generally conforming to the shape of the tissue to be enhanced.</p>	<p><b>said vessel has a shape generally conforming to the shape of the tissue to be enhanced:</b></p> <p><i>Compare Fig. 2 with Fig. 5 with Fig 14 with Fig. 13A with Fig. 13B;</i></p> <p>"One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36; and</p> <p>"A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38.</p> <p>Each of the referenced figures shows a vessel with a shape that generally conforms to the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel having a shape generally conforming to the shape of the tissue to be enhanced.</p>
<p><b>Claim 3.</b></p> <p>The apparatus in accordance with claim 1, wherein said vessel has a volume greater than the volume of tissue to be enhanced.</p>	<p><b>said vessel has a volume greater than the volume of tissue to be enhanced:</b></p> <p>Fig. 2, "12";</p> <p>Fig. 13A, "12";</p> <p>Fig. 13B, "12"; and</p> <p><u>"As the soft tissue enlarges</u>, the rate of enlargement increases due to a beneficial physical phenomenon. If the tissue only slightly protrudes into the dome as shown in Figure 3 and as is typically the initial condition, then the surface area 30 under the dome is only slightly larger than the normal area 32 at the dome</p>

	<p>opening. Therefore, the vacuum pressure <math>P_1</math> acts on a surface area 30 which approaches the minimal value of the normal area. As enlargement occurs, <u>more tissue protrudes into the dome 12</u> as shown in Figure 4 thereby providing more surface area 30 under the dome", ¶35 (emphasis added).</p> <p>In order to accommodate the enhancement or enlargement of the tissue, the dome or vessel is sized to have a volume larger than the volume of tissue to be enhanced. This is also shown in the referenced drawing figures where the dome is shown to be larger and thus surround the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel having a volume greater than the volume of tissue to be enhanced.</p>
<p><b>Claim 4.</b></p> <p>The apparatus in accordance with claim 1, wherein said vessel has a shape which is varied to control the shape of the tissue enhanced.</p>	<p><b>said vessel has a shape which is varied to control the shape of the tissue enhanced:</b></p> <p><i>Compare Fig. 2 with Fig. 5 with Fig 14 with Fig. 13A with Fig. 13B;</i></p> <p>"One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36;</p> <p>"A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38;</p> <p>"As shown in Figures 13A-B, still another application for the vacuum dome 12 with rim cushion 46 is to completely and entirely close an amputation stump.... this amputation stump may be a fresh wound and thereby promote healing of the surfaces as well as the growing of soft tissue to overlie <u>any bone which may even be exposed</u>. These kinds of injuries are often encountered where there has been an acute fingertip amputation", ¶48; and</p> <p>"As shown in Figure 14, still another application of the vacuum dome 12 with rim cushion 46 is as an aid in endoscopic surgery as is routinely performed in various kinds of plastic and vascular surgery", ¶49.</p> <p>In each of the referenced drawing figures and descriptions, the dome is shown with a different or varying shape to control the shape of the soft tissue to be enhanced. Thus, the specification</p>

	supports the recitation of the vessel having a shape which is varied to control the shape of the tissue enhanced.
<b>Claim 5.</b> The apparatus in accordance with claim 1, wherein said vessel is dome-shaped having a periphery to surround the tissue to be enhanced.	<p><b>said vessel is dome-shaped:</b>  Fig. 2, "12"; and "dome", ¶32.</p> <p><b>having a periphery:</b>  Fig. 2, "14"; and "rim", ¶32</p> <p><b>to surround the tissue to be enhanced:</b>  Fig. 9; and  "[T]he dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin", ¶42.</p> <p>As set forth above with respect to claim 1, the rim is affixed the open end of the dome. Thus, in order to allow the inward displacement of soft tissue into the dome, the rim must surround the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel being dome-shaped and having a periphery to surround the tissue to be enhanced.</p>
<b>Claim 6.</b> The apparatus in accordance with claim 1, wherein said vessel has an opening separate from said open end for connection to said source of vacuum.	<p><b>said vessel has an opening separate from said open end for connection to said source of vacuum:</b>  Fig 6, "14" and "64".</p>
<b>Claim 7.</b> The apparatus in accordance with claim 1, wherein said flexible mass includes an air pocket.	<p><b>said flexible mass includes an air pocket:</b>  Fig. 17A-D, "72";  "[T]his even distribution may be provided by a rim on the dome that has fluid-like properties. This cushion could be constructed with an <u>air or fluid bladder</u>, or any other type of membrane containing a gel-like fluid", ¶27 (emphasis added);  "[T]his shear force distribution may be accomplished with the use of a silicone gel or <u>inflated</u> membrane or bladder which has a thickness sufficient to allow its surface 70</p>

	<p>adjacent the soft tissue to shift laterally with respect to the rim", ¶40(emphasis added);</p> <p>"[T]he embodiment shown in Figure 9 may be comprised of a gel, <u>inflatable bladder</u>, etc....Alternative examples are shown in Figures 17A-D and include a foam 70 formed from a polyurethane or other similar substance, a ribbed or "swiss cheese" like construction where various <u>orifices</u> 72 are formed within a semi-rigid or flexible rim cushion 46. Also as shown in Figure 17D, a bellows 74 or accordion-like construction may be provided which could freely move and accommodate a reduced diameter upon deflexion thereof in response to the pulling of a vacuum within the dome"; ¶44 (emphasis added); and</p> <p>"This flexibility may be achieved for the use of a fluid-like cushion, <u>an air-filled fluid bladder</u>, a gel-like fluid, or such other construction and materials as would be effective to distribute the pressure substantially uniformly across the skin surface underlying the rim cushion 46", ¶47.</p> <p>An air filled fluid bladder or inflated membrane must include an air pocket. Thus, the specification supports the recitation of an air pocket.</p>
<p><b>Claim 8.</b></p> <p>Apparatus for enlarging soft living tissue comprising:</p>	<p><b>apparatus for enhancing living tissue:</b></p> <p><i>E.g.</i>, Fig. 1, "10";</p> <p>"soft tissue enlargement apparatus", ¶32; and</p> <p>"The dome may be conveniently located over an open wound in order to promote healing of the wound by enlarging the soft tissue under the dome. As the <u>soft tissue grows</u>, it promotes healing of the wound through acceleration of the closing thereof by soft tissue growth. As wounds may be received by a patient to any part of his body, the inventor's prior disclosed and <u>claimed invention</u> includes the use of a <u>dome over virtually any part of the human body.</u>" ¶13 (emphasis added).</p>

**Claim 8, Cont'd.**

a vessel having a rim defining an open end, the rim being adapted to encompass the tissue;

**a vessel:**

*E.g.*, Fig. 2, "12"; and  
"dome", ¶32

**a rim defining an open end:**

*E.g.*, Fig. 2, "14";  
"rim", ¶32; and

"This embodiment includes a rim 14 having a surface area 34 approximately equal to the normal area 32 of the dome opening thereby preventing medical complications to the soft tissue as long as the pressure is properly regulated within the dome 12", ¶36.

**the rim being adapted to encompass the tissue to be enhanced:**

*Compare Fig. 2 with Fig. 5 with Fig 14 with Fig. 13A with Fig. 13B;*

"One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36 (emphasis added); and

"A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38 (emphasis added).

**Claim 8, Cont'd.**

a source of vacuum connected to the vessel; and

**a source of vacuum:**

Fig. 1, "16; and

"a vacuum pump assembly 16 for creating a vacuum within the dome", ¶32.

**connected to said vessel:**

Fig. 1;

"Although two vacuum pump assemblies 16 may be used, one depending from each dome 12 so as to provide different pressures in the domes, the preferred embodiment places the domes in fluid communication with a conduit 50"; ¶37 (emphasis added); and

Fig. 6, "64"; "The cavity 62 between the dome 12 and sheet 60 may be evacuated as in the first general embodiment through a port 64 to apply the tensile force to the soft tissue"; ¶39.

**Claim 8, Cont'd.**

a flexible mass secured to the rim to distribute the forces exerted by said vacuum, thereby acting as a seal and force distributor between the vessel and the tissue adjacent the rim of said vessel.

**a flexible mass:**

Fig. 7, "46";

"A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or other soft, conforming type material", ¶37 (emphasis added);

"the dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin"; ¶42.

**secured to the rim:**

Fig. 7, "46"; and

"A gasket 46 may also be included about the rim 14", ¶37.

**to distribute the forces exerted by said vacuum, thereby acting as a seal and force distributor between the vessel and the tissue adjacent the rim of said vessel:**

Figs. 8-10, "46"; and

"Several forces are developed within the dome and about the rim as a result of evacuating air from the dome. A suction or tensile force  $F_s$  is developed within the dome 12 equal to the vacuum pressure  $P_1$  multiplied by the enclosed tissue surface area 30,  $A_s$ . The vector sum of the tensile force upon the tissue surface area 30 may be called the normal force  $F_1$  and is equal to the vacuum pressure multiplied by the normal area 32,  $A_1$  of the dome opening, i.e., the projected area bounded by the periphery 33, or  $F_1 = P_1 A_1$ . An opposing force  $F_2$  is imposed on the user by the rim 14 to balance the normal force  $F_1$  and is equal but opposite to the normal force. The contact pressure  $P_2$  of the rim 14 against the user is equal to this opposing force  $F_2$  divided by the annular rim surface area 34,  $A_2$ , i.e.,  $P_2 = F_2 / A_2$  or  $F_2 = P_2 A_2$ . As the magnitude of the opposing force is equal to the magnitude of the normal force,  $F_1 = F_2$  and  $P_1 A_1 = P_2 A_2$ .

	<p>Therefore, if the rim surface area 34, <math>A_2</math> is configured to be greater than or equal to the normal area 32, <math>A_1</math> at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum within the dome 12, i.e., <math>P_2=P_1</math>", ¶34.</p> <p>The gasket 46 absorbs the pressure exerted by the vacuum and distributes the force created by the vacuum. Thus, the specification in paragraph 34 makes it clear that the contact pressure of the rim against the user is decreased by increasing the surface area of the rim to which the gasket is secured.</p> <p>By application of simple physics, the increased surface area spreads or diffuses the forces created by the vacuum. This is supported by the drawings (Figs. 9, 10, 11A and 11B and 12) which show the rim 14 and gasket 46 as having much greater surface areas than the edge of the vessel (dome 12).</p> <p>The limitation of "seal" is supported by the statement, "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and <u>enhance the seal about the rim</u>", ¶37 (emphasis added).</p> <p>The above support from the specification makes clear that the gasket 46 is a flexible mass, is secured to the rim, distributes to forces exerted by the vacuum, and acts as both a seal and a force distributor between the vessel and the tissue adjacent the periphery of the vessel.</p> <p>See <i>also</i>, claim 1 above for additional support for claim 8.</p>
<p><b>Claim 9.</b></p> <p>The apparatus in accordance with claim 8 wherein the flexible mass comprises a gasket.</p>	<p><b>the flexible mass comprises a gasket:</b></p> <p>Fig. 7, "46"; and</p> <p>"A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or other soft, conforming type material", ¶37.</p>

<p><b>Claim 10.</b> The apparatus in accordance with claim 9 wherein the gasket comprises an inflated bladder.</p>	<p><b>the gasket comprises an inflated bladder:</b> Fig. 17A-D, "72"; and See also, claim 7 above for support for claim 10.</p>
<p><b>Claim 11.</b> The apparatus in accordance with claim 8 wherein the flexible mass comprises a flexible cushion.</p>	<p><b>the flexible mass comprises a flexible cushion:</b> Fig. 7, "46"; "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or <u>other soft, conforming type material</u>", ¶37 (emphasis added); and "[T]he dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin"; ¶42.</p>
<p><b>Claim 12.</b> The apparatus in accordance with claim 8 wherein the rim comprises a circumferential flange.</p>	<p><b>the rim comprises a circumferential flange:</b> Fig. 2, "14"; and "This embodiment includes a rim 14 having a surface area 34 approximately equal to the normal area 32 of the dome opening," ¶36. The rim must comprise a flange in order that the rim has a surface area and exert a force on soft tissue underlying the rim.</p>
<p><b>Claim 13.</b> An apparatus for enlarging living tissue comprising:</p>	<p><b>apparatus for enhancing living tissue:</b> <i>E.g.</i>, Fig. 1, "10"; "soft tissue enlargement apparatus", ¶32; and "The dome may be conveniently located over an open wound in order to promote healing of the wound by enlarging the soft tissue under the dome. As the <u>soft tissue grows</u>, it promotes healing of the wound through acceleration of the closing thereof by soft tissue growth. As wounds may be received by a patient to any part of his body, the inventor's prior disclosed and <u>claimed</u></p>

	<p><u>invention</u> includes the use of a <u>dome over virtually any part of the human body.</u>" ¶13 (emphasis added).</p>
<p><b>Claim 13, cont'd.</b> a vessel having an open end and adapted to encompass the tissue to be enlarged;</p>	<p><b>a vessel:</b> <i>E.g.</i>, Fig. 2, "12"; and "dome", ¶32</p> <p><b>an open end:</b> <i>E.g.</i>, Fig. 2, "14"; "rim", ¶32; and "This embodiment includes a rim 14 having a surface area 34 approximately equal to the normal area 32 of <u>the dome opening</u> thereby preventing medical complications to the soft tissue as long as the pressure is properly regulated within the dome 12", ¶36.</p> <p><b>and adapted to encompass the tissue to be enhanced:</b> <i>Compare</i> Fig. 2 <i>with</i> Fig. 5 <i>with</i> Fig 14 <i>with</i> Fig. 13A <i>with</i> Fig. 13B; and "One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36; "A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38.</p>
<p><b>Claim 13, cont'd.</b> a source of vacuum connected to said vessel; and</p>	<p><b>a source of vacuum:</b> Fig. 1, "16; and "a vacuum pump assembly 16 for creating a vacuum within the dome", ¶32.</p> <p><b>connected to said vessel:</b> Fig. 1; "Although two vacuum pump assemblies 16 may be used, one <u>depending</u> from each dome 12 so as to provide different pressures in the domes, the preferred embodiment places the</p>

	<p>domes in fluid communication with a conduit 50"; ¶37 (emphasis added); and</p> <p>Fig. 6, "64"; "The cavity 62 between the dome 12 and sheet 60 may be evacuated as in the first general embodiment through a port 64 to apply the tensile force to the soft tissue"; ¶39.</p>
<p><b>Claim 13, cont'd.</b></p> <p>a mass of elastic material affixed to the perimeter of the open end of said vessel to transform said vacuum applied to create a seal and force diffuser for the forces between the interior of the vessel and the tissue on which said vessel rests.</p>	<p><b>a mass of elastic material:</b></p> <p>Fig. 7, "46";</p> <p>"A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or <u>other soft, conforming type material</u>", ¶37 (emphasis added);</p> <p>"the dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin"; ¶42.</p> <p>Further, "elastic" means "capable of recovering size and shape after deformation." <i>Merriam Webster's Collegiate Dictionary</i>, 10<sup>th</sup> ed. © 1996. The specification states, "the cushion 46 should have inherent lateral flexibility to allow for <u>repeated bending, deflecting, and rotation</u>", ¶43. In view of the above, the limitation of "elastic" is supported by the specification.</p> <p><b>affixed to the perimeter of the open end of said vessel:</b></p> <p>Fig. 7, "46";</p> <p>"A gasket 46 may also be included about the rim 14", ¶37.</p> <p><b>to transform said vacuum applied to create a seal and force diffuser for the forces between the vessel and the tissue on which said vessel rests:</b></p> <p>Figs. 8-10, "46"; and</p> <p>"Several forces are developed within the dome and about the rim as a result of evacuating air from the dome. A suction or tensile force <math>F_s</math></p>

is developed within the dome 12 equal to the vacuum pressure  $P_1$  multiplied by the enclosed tissue surface area 30,  $A_s$ . The vector sum of the tensile force upon the tissue surface area 30 may be called the normal force  $F_1$  and is equal to the vacuum pressure multiplied by the normal area 32,  $A_1$  of the dome opening, i.e., the projected area bounded by the periphery 33, or  $F_1 = P_1 A_1$ . An opposing force  $F_2$  is imposed on the user by the rim 14 to balance the normal force  $F_1$  and is equal but opposite to the normal force. The contact pressure  $P_2$  of the rim 14 against the user is equal to this opposing force  $F_2$  divided by the annular rim surface area 34,  $A_2$ , i.e.,  $P_2 = F_2 / A_2$  or  $F_2 = P_2 A_2$ . As the magnitude of the opposing force is equal to the magnitude of the normal force,  $F_1 = F_2$  and  $P_1 A_1 = P_2 A_2$ .

Therefore, if the rim surface area 34,  $A_2$  is configured to be greater than or equal to the normal area 32,  $A_1$  at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum within the dome 12, i.e.,  $P_2 = P_1$ , ¶34.

Further, "transform" means "to change in character or condition." *Merriam Webster's Collegiate Dictionary*, 10<sup>th</sup> ed. © 1996.

The gasket 46 absorbs the pressure exerted by the vacuum and transforms the force created by the vacuum into a normal force. Thus, the specification in paragraph 34 makes it clear that the contact pressure of the rim against the user is decreased by increasing the surface area of the rim to which the gasket is affixed.

By application of simple physics, the increased surface area transforms the forces created by the vacuum. This is supported by the drawings (Figs. 9, 10, 11A and 11B and 12) which show the rim 14 and gasket 46 as having much greater surface areas than the edge of the vessel (dome 12).

The limitation of "seal" is supported by the statement, "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim", ¶37 (emphasis added).

The above support from the specification makes clear that the gasket 46 is a flexible mass,

	<p>is affixed to the open end of the vessel, transforms the pressure exerted by the vacuum, and acts as both a seal and a force diffuser between the vessel and the tissue on which the vessel rests. The above support also shows that the vacuum force developed in the dome is "transformed" into a normal force applied to the patient through the rim 14. Thus, the specification supports the recitation of "transform said vacuum".</p> <p><i>See also, claim 1 above for support for claim 13.</i></p>
<p><b>Claim 14.</b></p> <p>The apparatus in accordance with claim 13, wherein said vessel has a shape generally conforming to the shape of the tissue to be enlarged.</p>	<p><b>said vessel has a shape generally conforming to the shape of the tissue to be enhanced:</b></p> <p><i>Compare Fig. 2 with Fig. 5 with Fig. 14 with Fig. 13A with Fig. 13B;</i></p> <p>"One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36; and</p> <p>"A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38.</p> <p>Each of the referenced figures shows a vessel with a shape that generally conforms to the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel having a shape generally conforming to the shape of the tissue to be enhanced.</p>
<p><b>Claim 15.</b></p> <p>The apparatus in accordance with claim 13, wherein said vessel has an interior volume greater than the volume of the tissue to be enlarged.</p>	<p><b>said vessel has a volume greater than the volume of tissue to be enhanced:</b></p> <p>Fig. 2, "12";</p> <p>Fig. 13A, "12";</p> <p>Fig. 13B, "12"; and</p> <p><u>"As the soft tissue enlarges</u>, the rate of enlargement increases due to a beneficial physical phenomenon. If the tissue only slightly protrudes into the dome as shown in Figure 3 and as is typically the initial condition, then the surface area 30 under the dome is only slightly larger than the normal area 32 at the dome</p>

	<p>opening. Therefore, the vacuum pressure <math>P_1</math> acts on a surface area 30 which approaches the minimal value of the normal area. As enlargement occurs, <u>more tissue protrudes into the dome 12</u> as shown in Figure 4 thereby providing more surface area 30 under the dome", ¶35 (emphasis added).</p> <p>In order to accommodate the anticipated enhancement or enlargement of the tissue, the dome or vessel is sized to have a volume larger than the volume of tissue to be enhanced. This is also shown in the referenced drawing figures where the dome is shown to be larger and thus surround the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel having a volume greater than the volume of tissue to be enhanced.</p>
<p><b>Claim 16.</b></p> <p>The apparatus in accordance with claim 13, wherein said vessel has a shape which is varied to control the configuration of the resultant enlargement.</p>	<p><b>said vessel has a shape which is varied to control the shape of the tissue enhanced:</b></p> <p><i>Compare Fig. 2 with Fig. 5 with Fig 14 with Fig. 13A with Fig. 13B;</i></p> <p>"One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36;</p> <p>"A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38;</p> <p>"As shown in Figures 13A-B, still another application for the vacuum dome 12 with rim cushion 46 is to completely and entirely close an amputation stump.... this amputation stump may be a fresh wound and thereby promote healing of the surfaces as well as the growing of soft tissue to overlie <u>any bone which may even be exposed</u>. These kinds of injuries are often encountered where there has been an acute fingertip amputation", ¶48; and</p> <p>"As shown in Figure 14, still another application of the vacuum dome 12 with rim cushion 46 is as an aid in endoscopic surgery as is routinely performed in various kinds of plastic and vascular surgery", ¶49.</p> <p>In each of the referenced drawing figures and descriptions, the dome is shown with a different or varying shape to control the shape of the soft tissue to be enhanced. Thus, the specification</p>

	supports the recitation of the vessel having a shape which is varied to control the shape of the tissue enhanced.
<b>Claim 17.</b> The apparatus in accordance with claim 13, wherein said vessel is dome-shaped and open at one end to encircle the tissue to be enlarged.	<p><b>said vessel is dome-shaped:</b>  Fig. 2, "12"; and "dome", ¶32.</p> <p><b>having a periphery:</b>  Fig. 2, "14"; and "rim", ¶32</p> <p><b>to surround the tissue to be enhanced:</b>  Fig. 9; and  "[T]he dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin", ¶42.</p> <p>As set forth above with respect to claim 1, the rim is affixed the open end of the dome. Thus, in order to allow the inward displacement of soft tissue into the dome, the rim must surround the soft tissue to be enhanced. Thus, the specification supports the recitation of the vessel being dome-shaped and having a periphery to surround the tissue to be enhanced.</p>
<b>Claim 18.</b> The apparatus in accordance with claim 13, wherein said vessel has an opening separate from said open end for connection to a source of vacuum.	<p><b>said vessel has an opening separate from said open end for connection to said source of vacuum:</b>  Fig 6, "14" and "64".</p>

**Claim 19.**

The apparatus in accordance with claim 13, wherein said elastic material surrounds an air pocket.

**said flexible mass includes an air pocket:**

Fig. 17A-D, "72";

"[T]his even distribution may be provided by a rim on the dome that has fluid-like properties. This cushion could be constructed with an air or fluid bladder, or any other type of membrane containing a gel-like fluid", ¶27 (emphasis added);

"[T]his shear force distribution may be accomplished with the use of a silicone gel or inflated membrane or bladder which has a thickness sufficient to allow its surface 70 adjacent the soft tissue to shift laterally with respect to the rim", ¶40(emphasis added);

"[T]he embodiment shown in Figure 9 may be comprised of a gel, inflatable bladder, etc....Alternative examples are shown in Figures 17A-D and include a foam 70 formed from a polyurethane or other similar substance, a ribbed or "swiss cheese" like construction where various orifices 72 are formed within a semi-rigid or flexible rim cushion 46. Also as shown in Figure 17D, a bellows 74 or accordion-like construction may be provided which could freely move and accommodate a reduced diameter upon deflexion thereof in response to the pulling of a vacuum within the dome"; ¶44 (emphasis added); and

"This flexibility may be achieved for the use of a fluid-like cushion, an air-filled fluid bladder, a gel-like fluid, or such other construction and materials as would be effective to distribute the pressure substantially uniformly across the skin surface underlying the rim cushion 46", ¶47.

An air filled fluid bladder or inflated membrane must include an air pocket. Thus, the specification supports the recitation of an air pocket.

<p><b>Claim 20.</b> An apparatus for enhancing living tissue comprising:</p>	<p><b>apparatus for enhancing living tissue:</b>  <i>E.g.</i>, Fig. 1, "10";  "soft tissue enlargement apparatus", ¶32; and  "The dome may be conveniently located over an open wound in order to promote healing of the wound by enlarging the soft tissue under the dome. As the <u>soft tissue grows</u>, it promotes healing of the wound through acceleration of the closing thereof by soft tissue growth. As wounds may be received by a patient to any part of his body, the inventor's prior disclosed and <u>claimed invention</u> includes the use of a <u>dome over virtually any part of the human body.</u>" ¶13 (emphasis added).</p>
<p><b>Claim 20, cont'd.</b> a vessel having an open end and adapted to encompass the tissue to be enlarged;</p>	<p><b>a vessel:</b>  <i>E.g.</i>, Fig. 2, "12"; and  "dome", ¶32</p> <p><b>an open end:</b>  <i>E.g.</i>, Fig. 2, "14";  "rim", ¶32; and  "This embodiment includes a rim 14 having a surface area 34 approximately equal to the normal area 32 of <u>the dome opening</u> thereby preventing medical complications to the soft tissue as long as the pressure is properly regulated within the dome 12", ¶36.</p> <p><b>and adapted to encompass the tissue to be enlarged:</b>  <i>Compare</i> Fig. 2 <i>with</i> Fig. 5 <i>with</i> Fig 14 <i>with</i> Fig. 13A <i>with</i> Fig. 13B; and  "One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2", ¶36; "A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis"; ¶38.</p>

<p><b>Claim 20, cont'd.</b> a source of vacuum connected to said vessel;</p>	<p><b>a source of vacuum:</b> Fig. 1, "16"; and "a vacuum pump assembly 16 for creating a vacuum within the dome", ¶32.</p> <p><b>connected to said vessel:</b> Fig. 1; "Although two vacuum pump assemblies 16 may be used, one <u>depending</u> from each dome 12 so as to provide different pressures in the domes, the preferred embodiment places the domes in fluid communication with a conduit 50"; ¶37 (emphasis added); and Fig. 6, "64"; "The cavity 62 between the dome 12 and sheet 60 may be evacuated as in the first general embodiment through a port 64 to apply the tensile force to the soft tissue"; ¶39.</p>
<p><b>Claim 20, cont'd.</b> a flexible mass attached to the open end of the vessel to act as a seal and force distributor between the vessel and the tissue adjacent the periphery of said vessel.</p>	<p><b>a flexible mass:</b> Fig. 7, "46"; "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or <u>other soft, conforming type material</u>", ¶37 (emphasis added); "the dome 12 is supported at a modified rim 14 with an underlying gasket (hereinafter referred to as "cushion") 46 which is sufficiently flexible to allow inward displacement as the skin surface is drawn into the dome 12 by the effect of the vacuum therewithin"; ¶42.</p> <p><b>attached to the open end of the vessel:</b> Fig. 7, "46"; "A gasket 46 may also be included about the rim 14", ¶37.</p> <p><b>to act as a seal and force distributor between the vessel and the tissue adjacent the periphery of said vessel:</b> Figs. 8-10, "46"; and "Several forces are developed within the dome and about the rim as a result of evacuating air from the dome. A suction or tensile force <math>F_s</math></p>

is developed within the dome 12 equal to the vacuum pressure  $P_1$  multiplied by the enclosed tissue surface area 30,  $A_s$ . The vector sum of the tensile force upon the tissue surface area 30 may be called the normal force  $F_1$  and is equal to the vacuum pressure multiplied by the normal area 32,  $A_1$  of the dome opening, i.e., the projected area bounded by the periphery 33, or  $F_1 = P_1 A_1$ . An opposing force  $F_2$  is imposed on the user by the rim 14 to balance the normal force  $F_1$  and is equal but opposite to the normal force. The contact pressure  $P_2$  of the rim 14 against the user is equal to this opposing force  $F_2$  divided by the annular rim surface area 34,  $A_2$ , i.e.,  $P_2 = F_2 / A_2$  or  $F_2 = P_2 A_2$ . As the magnitude of the opposing force is equal to the magnitude of the normal force,  $F_1 = F_2$  and  $P_1 A_1 = P_2 A_2$ . Therefore, if the rim surface area 34,  $A_2$  is configured to be greater than or equal to the normal area 32,  $A_1$  at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum within the dome 12, i.e.,  $P_2 = P_1$ , ¶34.

The gasket 46 distributes the pressure exerted by the vacuum and the force created by the vacuum. Thus, the specification in paragraph 34 makes it clear that the contact pressure of the rim against the user is decreased by increasing the surface area of the rim to which the gasket is affixed.

By application of simple physics, the increased surface area distributes the forces created by the vacuum. This is supported by the drawings (Figs. 9, 10, 11A and 11B and 12) which show the rim 14 and gasket 46 as having much greater surface areas than the edge of the vessel (dome 12).

The limitation of "seal" is supported by the statement, "A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim", ¶37 (emphasis added).

The above support from the specification makes clear that the gasket 46 is a flexible mass, is attached to the open end of the vessel, and acts as both a seal and a force distributor between the vessel and the tissue adjacent the

	periphery of the vessel.
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**Interfering Subject Matter**

The Kaiser Patent issued March 28, 2000, based on application Serial No. 08/915,540, filed August 13, 1997. The effective filing date of the present application is earlier than that of the Kaiser patent. Many claims of the present application correspond exactly or substantially to claims of the Kaiser patent. In particular, claims 1-7 of the present application are identical to claims 1-7 of the Kaiser patent, and claims 13-19 of the present application correspond exactly to claims 20-26 of the Kaiser patent. Claim 8 of the present application corresponds substantially to claim 1 of the Kaiser patent. Claim 10 of the present application corresponds substantially to claim 7 of the Kaiser patent.

Claim 20 of the present application corresponds substantially to claims 1 and 20 of the Kaiser patent. Applicant submits that a suitable count for an interference involving the present application and the Kaiser patent would be identical to applicant's claim 20. All claims of the Kaiser patent correspond substantially to applicant's claim 20.


Claims 8-12 of the Kaiser patent are directed to the same invention as claim 7 of the Kaiser patent because claim 7 either alone or in combination with the relevant prior art renders obvious claims 8-12. Kaiser's claims 13-19 are directed to the same patentable invention as Kaiser's claim 1 because claim 1 either alone in combination with the relevant prior art renders obvious claims 13-19. Kaiser's claims 27-31 are directed to the same patentable invention as Kaiser's claim 26 because claim 26 either alone or in combination with the relevant prior art renders obvious claims 27-31. Kaiser's claims 32-38 are directed to the same patentable invention as Kaiser's claim 20 because claim 20 either alone or in combination with the relevant prior art renders obvious claims 32-38.

**CONCLUSION**

In view of the above and the Notice of Interfering Subject Matter filed by Applicant on March 27, 2001, pursuant to 37 C.F.R. § 1.607, Applicant respectfully requests the interference be declared with U.S. Pat. No. 6,042,537, issued March 28, 2000, to Kaiser (App. Ser. No. 08/915,540, filed August 13, 1997).

Respectfully submitted,

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